

From: Zoltan Massay-Kosubek <zoltan@epha.org>
Sent: 18 October 2013 14:43
To: SCHNICHELS Dominik (SANCO)
Cc: [REDACTED]
Subject: Re: potential meeting / phone call about the regulation of e-cigarettes in light of the ongoing TPD debate
Attachments: EPHA_position_on_the_TPD_May_2013.pdf
Categories: TO REGISTER

Dear Dominik,

Sorry, my mistake, I included the wrong hyperlink in my previous e-mail.

The EPHA position is available on-line and I send it attached to that e-mail, as well.

http://www.epha.org/IMG/pdf/EPHA_position_on_the_TPD_May_2013-4.pdf

I am looking forward to your response and have a nice week-end!

Best wishes,

Zoltán

On 18 October 2013 14:30, <Dominik.Schnichels@ec.europa.eu> wrote:

Dear Zoltan,

Thanks for your mail. The EPHA TPD position was not attached. Can you please send it. We will get back to you regarding a potential meeting as soon as possible.

Kind regards

Dominik

From: Zoltan Massay-Kosubek [mailto:zoltan@epha.org]
Sent: Friday, October 18, 2013 10:55 AM

To: SCHNICHELS Dominik (SANCO); [REDACTED]

Subject: potential meeting / phone call about the regulation of e-cigarettes in light of the ongoing TPD debate

Dear Colleagues,

My name is Zoltán Massay-Kosubek, I work for the European Public Health Alliance (EPHA) and I am contacting you in respect of the different legislative options of e-cigarettes with regard to the ongoing discussion on the Tobacco Products Directive (TPD). I am wondering, would it be possible to set up a short meeting or - since EPHA is located in Brussels - having a phone call about this important issue?

I am writing all of you because you had a meeting in June about e-cigarettes with some electronic cigarette industry representatives so you might be responsible for that issue in DG SANCO (http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf). Am I right?

Please find the EPHA TPD position on TPD here - which have a section on e-cigarettes, as well.

http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf

I think, an exchange of views with you about possible regulatory options would be extremely helpful since both the public health and the tobacco control community are concerned about the benefits and risks of e-cigarettes and due to the ongoing TPD debate, identifying the best regulatory option would be crucial.

Thank you very much for your feedback in advance.

Best wishes,

Zoltán

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Mr. Zoltán MASSAY-KOSUBEK

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EPHA is the European Platform bringing together public health organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations.

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Revision of the Tobacco Products Directive



EPHA Position Paper

Revision of the Tobacco Products Directive

The **European Public Health Alliance (EPHA)** is the European Platform **bringing together public health** organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations. Our membership includes representatives at international, European, national, regional and local level.

EPHA's mission is **to protect and promote public health in Europe**. EPHA brings together organisations across the public health community, to share learning and information and to bring a public health perspective to European decision-making. We help build capacity in civil society participation across Europe in the health field, and work to empower the public health community in ensuring that the health of European citizens is protected and promoted by decision-makers. **Our aim is to ensure health is at the heart of European policy and legislation.**

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Summary

Directive 2001/37/EC¹ has been the framework regulating the manufacture, presentation and sale of tobacco products in the 27 Member States of the European Union (EU) since 2001. The 2001 Directive (the Tobacco Products Directive) had two established objectives: facilitating the functioning of the internal market in the tobacco products sector and ensuring a high level of public health.

In 2005, the EU ratified the World Health Organization's Framework Convention on Tobacco Control (FCTC). In 2012, all 27 Member States of the EU had signed and ratified the text, therefore rendering the provisions of the FCTC applicable to them. The 2001 Tobacco Products Directive was adopted prior to the EU commitment under the FCTC, and therefore, the revision of the Directive presents an **opportunity for the EU to bring its main tobacco policy framework in line with its international obligations.**

Recommendations

EPHA recommends the following as part of the revision of Directive 2001/37/EC:

- **Mandatory plain packaging:** combined health warnings (text and picture) should cover **80%** of both front and back of tobacco packages
- **All additives should be banned**, including flavourings
- The status quo on **snus should be maintained**
- **Nicotine containing products including e-cigarettes should be regulated:** the pharmaceutical legislation (*Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use*) could provide an appropriate framework for regulating the quality, safety and efficacy of NCPs but we do not exclude other approaches that could equally achieve the objectives outlined above
- **Online sale of tobacco products should be banned**

¹ Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

Revision of the Tobacco Products Directive

Introduction

The new EU Tobacco Products Directive is an **essential piece of legislation** and can play a key role in achieving the objectives of “*Europe 2020 – Europe’s Growth Strategy*”: to keep people healthy and active longer, to help people prevent avoidable diseases and premature death and to have a positive impact on productivity and thus competitiveness.

With this Directive, the **EU has the possibility to change the burden of disease for the new generation**. By restricting the ability of economic operators to market lethal products to children and young people and thus secure them as contributors to their benefits², the EU is in a position to show political leadership and allow children and young people to grow up in an environment that is clear on what tobacco products are: **the only products that, if used the way they are supposed to be, kill one of their two long-term users**.

Tobacco in a few figures:

- 700 000 deaths per year in the EU³,
- 13 million people suffering from the main tobacco-related diseases⁴,
- In 2012, 28 % of all EU citizens smoked, 29 % of people aged 15-24 years⁵,
- A total of €25.3 billion spent every year in healthcare in Europe⁶,
- €8.3 billion of annual productivity loss⁷,
- 75% of the EU population in favour of stricter tobacco measures⁸,

EPHA recalls that the EU as well as each of its 27 Member States are signatories to and have ratified the **World Health Organization Framework Convention on Tobacco Control (FCTC)**. The FCTC includes articles on the regulation of the contents of tobacco products (Article 9), packaging and labelling of tobacco products (Article 11) and Tobacco advertising, promotion and sponsorship (Article 13) and the EU and its Member States must implement them.

² In 2012, the profits of Philip Morris and British American Tobacco, two of the main tobacco companies, were estimated to almost €14 billion

³ Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products. European Commission December 2012. http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf

⁴ http://europa.eu/rapid/press-release_MEMO-11-349_en.htm?locale=en#footnote-1footnote-1

⁵ “Attitudes of Europeans towards tobacco”, Special Eurobarometer 385, March 2012

⁶ James Reilly, Minister of Health intervention, ENVI public hearing on the Tobacco Products Directive, 25 February 2013

⁷ James Reilly, Minister of Health intervention, ENVI public hearing on the Tobacco Products Directive, 25 February 2013

⁸ Eurobarometer Tobacco, Special Eurobarometer 332, 2010

Ingredients and additives

Using additives, including flavouring agents in tobacco products is an old industry practice⁹ that consists of adding substances in order to make products more palatable, enhance their attractiveness and create the impression they are less harmful than they really are. **Vanilla, caramel, watermelon, candy apple, cotton candy and sweets cognac** are some of the flavours currently available on the market associating tobacco products to food products, sweets in particular, and thereby increasing their attractiveness, especially to young people, their primary target¹⁰. “Some flavours bring an increased social acceptance via their pleasant aroma and aftertaste” concluded a Philip Morris study¹¹. Tobacco products containing **menthol** facilitate a deeper inhalation which may enhance the addictiveness of nicotine¹². Similarly, **sugars**, whose content in tobacco products have been increased over years, produce a substance (acetaldehyde) that, when burned is largely contributing to the addictiveness of tobacco products¹³¹⁴.

A recent review of more than 600 additives concluded that more than 100 of them were known to:

“have pharmacological actions that camouflage the odour of environmental tobacco smoke emitted, enhance or maintain nicotine delivery, could increase the addictiveness and mask symptoms and illnesses associated with smoking behaviours.”¹⁵

“From the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help to make tobacco products attractive” explain the guidelines of FCTC articles 9¹⁶.

While there is a broad consensus that **tobacco products should not include any elements that are misleading consumers** as to their lethal nature, it is **not acceptable** that people are able to find **tobacco products marketed as sweets, associated with energy and vitality** (for those that contain caffeine, taurine and guarana), marketed as having some **beneficial effects** (e.g increase mental alertness and physical performance, help to keep the teeth white, etc.).

In recent years there have been developments in the tobacco industry which increasingly make use of ingredients to make their products more attractive to young people such as ingredients colouring the smoke to match the colour of the cigarette paper¹⁷. **Beyond increasing products attractiveness** and youth initiation, such ingredients transform tobacco products into even more complex chemical mixtures and thereby may **further increase their harmful effects**.

Over recent years there has been an increasing global trend towards regulating tobacco ingredients and additives, in particular the ones attracting young people: France banned vanilla cigarettes in 2009; Canada prohibited most flavouring agents in 2010¹⁸; the United States banned cigarettes containing fruit, confectionary or clove flavours in 2009¹⁹; and Brazil²⁰ became the first country in the world to ban all flavours (menthol, honey, cherry, tutti-frutti and chocolate) **and additives** (ammonia, sweeteners, colours, vitamins and essential fatty acids) in 2012. It is therefore

⁹ Leffingwell JC, Young HJ, Bernasek E. Tobacco flavoring for smoking products. Winston-Salem, NC: RJ Reynolds Tobacco Company, 1972. Retrieved online from the Legacy Tobacco Documents Library <http://legacy.library.ucsf.edu/tid/avr03c00>, accessed 28 February 2007).

¹⁰ Cummings KM et al. Marketing to America's youth: evidence from corporate documents. *Tobacco Control*, 2002, 11(Suppl. 1):i5–i17.

¹¹ Philip Morris. “New flavors qualitative research insights”, October 1992. Bates No. 2023163698-2023163710.

¹² Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Opinion, European Commission, 2010

¹³ Philip Morris, Termination of chronic acetaldehyde administration does not result in a physical dependence syndrome. Tobacco Resolution, Bates Number 1000060695-60704

¹⁴ Philip Morris 1982, Evaluation of the DeNoble nicotine acetaldehyde Data, Tobacco Resolution, BN 2056144727-4728

¹⁵ Rabinoff MD, Caskey N, Rissling A, Park C. Pharmacological and Chemical Effects of Cigarette Additives. *Am J Public Health* 2007; 97:1981-91.

¹⁶ http://www.who.int/fctc/guidelines/Guidelines_Articles9and10_COP5.pdf

¹⁷ De Standaard. Belgium. 5 December 2011

¹⁸ http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2010/2010_112-eng.php

¹⁹ US Family Smoking Prevention Tobacco Control Act, 2009

²⁰ http://www.fctc.org/index.php?option=com_content&view=article&id=728:brazil-bans-flavoured-tobacco&catid=233:product-regulation&Itemid=237

essential that the EU does not undermine efforts accomplished by Member States to protect the health of their population and contributes to **harmonise today's segmented market** by **prohibiting all additives**.

Labelling and packaging

Tobacco packaging is the first and principal link between consumers and manufacturers. It plays a critical role in smoking uptake, in particular by the young as the main marketing channel tobacco industries can use to attract and retain users.

As stated in the Commission proposal for a revised Directive, *"the purpose of the proposal is to regulate tobacco products in such a way they do not encourage young people to start smoking"*. Therefore, it is crucial Members of the European Parliament and Member States use the opportunity offered by **the** revision of the text to follow the examples set by an increasing number of countries and **demonstrate their commitment to healthy policy making by further regulating the main interface between smokers and manufacturers: tobacco packages**.

Standardised/ plain packaging

Based on the latest evidence available on tobacco packages as well as the Framework Convention on Tobacco Control guidelines²¹, **the European public health community strongly recommends the introduction of plain standardised packaging**. Considered in an increasing number of Member States - the United Kingdom, Belgium, France, Finland at the moment – plain standardised packages consist of **harmonising the size and shape of tobacco packages and removing all branding** (see picture).

Not only would plain standardised packaging prevent the promotion of smoking through branding, it would also reinforce the health warning messages, whose effectiveness have been detailed in the following paragraph²². Furthermore, the measure is **broadly supported by the EU population**²³.

Health warnings

Text only warning messages are not as effective as graphic warnings²⁴. Pictures, strong emotion-inducing pictures such as children and unborn babies illustrations, and fear-inducing pictures are proven to be the most effective in getting consumers' attention²⁵ and thus memory. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message.

Warning size

Increasing the size of warning messages enhances the effectiveness of the warning amongst both young and adult smokers and non smokers. **Warning messages that cover 100% of the pack are**

²¹ "Parties should consider adopting plain packaging requirements to eliminate the effects of advertising and promotion on packaging". (GL Article 13)

²² N.B: Implementing health warnings on 75% of tobacco packages would leave space for the trademarks.

²³ Eurobarometer Tobacco, Special Eurobarometer 332, 2010

²⁴ Sambrook Research International, A review of the science base to support the development of health warnings for tobacco packages, prepared for the European Commission, 2009

²⁵ Sambrook Research International, A review of the science base to support the development of health warnings for tobacco packages, prepared for the European Commission, 2009

significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack²⁶.

In 2010, **Uruguay** implemented health warnings covering **80% of both front and back of tobacco packages**. Since then, cigarette consumption decreased by an average 4.3% per year, while in its neighbour country, Argentina, it decreased by 0.6%. Similarly, the prevalence of tobacco use decreased by 3.3% a year, more than twice as much as Argentina²⁷.

As of 2013, **Sri Lanka** will also cover its packages with warnings covering 80% of tobacco packages²⁸.

The European public health community strongly advises Members of the European Parliament and Member States to adopt **combined health warnings (picture and text) to cover 80% of both sides of tobacco packages**. This measure would be in line with the population preferences - **75% of EU citizens being in favour of mandatory pictorial warnings**²⁹ - and ensure the best health outcomes possible.

For the sake of coherence, all tobacco products should be labelled in a similar and homogenous way as far as health warnings are concerned. Therefore, we recommend the **elimination of all exemptions** (currently applying to smokeless tobacco products, cigars, pipe, etc.) and **the implementation of a systematic labelling system for all tobacco products**.

Tar, nicotine and carbon monoxide (TNCO) labelling

Tar, nicotine and carbon monoxide (TNCO) current quantitative labelling promote the mistaken belief that some cigarette brands are less harmful than others. Therefore, **numerical measurements should be replaced by descriptive information on the hazardous effects of tobacco constituents and emissions**, as proposed by the European Commission.

Traceability and security features

The European public health community welcomes the effective implementation of the power delegated to the European Commission to adopt technical measures related to the traceability, identification and security features of tobacco packs. Illicit trade of tobacco is a considerable burden, both in terms of the public health impact of the consumption of even more harmful products than tobacco products themselves and in terms of its associated societal cost (organised crime, social and economic poverty, lost government revenue).

While we welcome the Commission provision, it could be considerably improved by targeting **visible and invisible security features, by applying unique identifiers on the outside packaging of tobacco products such as cartons, master cases and pallets** and by ensuring that the **storage and access to such data is independent from tobacco companies**. **Strengthening the traceability and identification features of tobacco packs is one of the most effective measures Member States can use to combat illicit trade**. Moreover, this is in line with article 15 of the Framework Convention on Tobacco Control as well as the FCTC protocol to eliminate illicit trade in tobacco products³⁰ adopted in November 2012.

²⁶ Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey, Hammond et al., Tob Control. 2006 June; 15(Suppl 3): iii19–iii25.

²⁷ Tobacco control campaign in Uruguay: a population-based trend analysis, Abascal W et al., Lancet 2012 Nov, 380(9853):1575-82

²⁸ <http://www.tobaccocontrolaws.org/files/live/Sri%20Lanka/Sri%20Lanka%20-%20P%26L%20Regs%202012.pdf>

²⁹ Eurobarometer Tobacco, Special Eurobarometer 332, 2010

³⁰ Protocol to Eliminate Illicit Trade in Tobacco Products, World Health Organization, 2012

Tobacco for oral use

Snus is a moist powder tobacco product consumed placed under the upper lip. It is a traditional product mainly used in Sweden. Like all traditional products, it corresponds to cultural norms, behaviours and habits that 26 out of the 27 Member States of the EU are not familiar with.

The general conclusion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report on 'Health Effects of Smokeless Tobacco Products' (published in February 2008) is that:

"STP are addictive and their use is hazardous to health. Evidence on the effectiveness of STP as a smoking cessation aid is insufficient, and relative trends in progression from STP into and from smoking differ between countries. It is thus not possible to extrapolate the patterns of tobacco use from one country where oral tobacco is available to other countries."

According to the Commission Impact Assessment³¹:

"there is no compelling evidence that lifting the ban on oral tobacco would lead to reduced smoking prevalence. On the contrary it has been suggested that smokeless tobacco products can play a role in the uptake of tobacco consumption or result in a combined consumption together with tobacco products... Thus, maintaining the ban on snus is considered to be the only effective measure to contain the use of this product and discourage the uptake of smokeless tobacco products and thus nicotine addiction amongst non-smokers and young people."

Considering the above mentioned evidence, the European public health community urges Members of the European Parliament and Member States to **maintain the status quo on snus, i.e. to allow it in Sweden where it is a traditional product but not introducing it onto the EU market**. This would support efforts made by Member States that already banned or announced a ban of oral tobacco due to their harmful effects.

Cross-border distance sales of tobacco products

Online sale is a part of the market that poses a number of challenges. Every hour, new websites are being created, existing ones disappear and controlling these websites is unlikely to be successful, notably due to the considerable size of the market. The internet offers unlimited opportunities and answers to all demands which makes it an area difficult, not to say impossible, to fully regulate.

According to the World Health Organization (WHO)³², internet sales of tobacco:

"translate into global penetration of tobacco products, unprecedented access of cigarette to minors, cheap cigarettes through tax avoidance and smuggling, and unfettered advertising, marketing and promotion".

For these reasons, and to ensure the EU population, children and young people in particular, is protected from the consequences of easily accessible potentially very harmful products, the European Public Health Alliance **recommends to ban the online sale of tobacco products**.

³¹ Commission staff working document, Impact Assessment, Accompanying the document "Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products", 2012

³² <http://www.who.int/tobacco/en/atlas23.pdf>

Nicotine containing products

The revision of the Tobacco Products Directive provides an opportunity to apply an appropriate regulatory regime for novel nicotine containing products (NCPs). We have seen, over recent years, an array of new products being developed, such as electronic cigarettes. These products have the potential to be used as harm reduction tools for adult smokers, although they must be properly regulated in terms of:

- manufacturing standards,
- composition (including flavours) and consistent dosage,
- responsible marketing and non-promotional packaging,
- sales restrictions (age requirement),
- instructions for use and information about risks to consumers.

Regulation is important to avoid these products being marketed to appeal non-smokers, especially young people.

In order to guarantee that NCPs are used in the most effective way and potential misuse is prevented, it is necessary to regulate their use in an appropriate and proportionate framework.

EPHA believes that the pharmaceutical legislation (*Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use*) could provide an appropriate framework for regulating the quality, safety and efficacy of NCPs but we do not exclude other approaches that could equally achieve the objectives outlined above. The Commission's proposal, however, to differentiate between NCPs on the basis of nicotine levels in the product does not reflect the reality that products may be used in different ways to attain varying levels of nicotine intake.

Conclusion

The revision of the EU Tobacco Products Directive represents a unique opportunity for the EU to bring its policies in line with its international obligations. It is time for policy makers to demonstrate their commitment to healthy policy making and prioritise the health of 500 million people – and in particular protecting the young against the uptake of health-damaging products - over the profits of economic operators selling a product that, since you began reading this document, killed 300 persons.